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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/828,739	04/09/2001	Avi J. Ashkenazi	P1468R1D1	1184

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EXAMINER

SAUNDERS, DAVID A

ART UNIT PAPER NUMBER

1644

DATE MAILED: 10/10/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

828,739

Applicant(s)

ASHKENAZI et al

Examiner

SAUNDERS

Group Art Unit

1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☐ Responsive to communication(s) filed on _____.
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-21 is/are pending in the application.
- ☐ Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-21 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☒ The drawing(s) filed on 4/9/01 is/are objected to by the Examiner. DRAFTSMAN.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 3
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

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The claims pending and under examination are 1-21.

> Claim 2 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Given the definitions of "monoclonal" (page 9) and of "isolated nucleic acid" (page 22) given by applicant, it is not seen how an antibody encoded by an isolated nucleic acid can be any kind of antibody other than a monoclonal antibody. Thus claim 2 fails to further limit claim 1.

> Claims 1-21 are rejected under 112 sixth paragraph.

Since the claims cover no particular DNA sequence but, rather, all DNA sequences which achieve a particular result, without defining what means will do so, these claims are essentially single means claims. *Fiers v. Sugano* 25 USPQ2d 1601.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 17 is rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Applicant has shown no utility for a method of merely producing an antibody from a host cell in a culture medium. The antibody in the cultured host cells and or medium has no disclosed or well established and know use. The antibody has no use unless it is further recovered from the

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host cell culture (as in claim 18). Therefore the method of claim 17 has no utility unless it is conducted in conjunction with the method of claim 18.

➤ Claim 17 is also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

➤ Claims 1-21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant's claims may all be considered as single means claims.

As such, these claims fail to comply with the enablement requirement of 112, first paragraph. In re Hyatt 218 USPQ 195.

➤ Claims 1-21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant failed to possess the claimed DNA, vector, host cells and methods of use thereof.

Applicant's specification has merely shown possession of three hybridoma cell lines that secrete monoclonal antibodies in accord with the nature of the disclosed antibodies. However,

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with respect to nucleic acids (DNA), applicant has merely reviewed several art known methods of providing such DNA, such as obtaining the encoding DNA from hybridoma cell lines, from phage display libraries, etc. Such methods, however, do not provide a description of its structure (sequence). Specification containing statement that claimed DNA sequence is part of invention and reference to potential method for isolating sequence does not satisfy written description requirement of 35 U.S.C. 112, since specification does not describe DNA itself. *Fiers v. Sugano* 25 USPQ2d 1601.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

(f) he did not himself invent the subject matter sought to be patented.

(g)(1) during the course of an interference conducted under section 135 or section 291, another inventor involved therein establishes, to the extent permitted in section 104, that before such person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or (2) before such person's invention thereof, the invention was made in this country by another inventor who had

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not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

Claims 1-12 and 15-21 are rejected under 35 U.S.C. 102(e) or (g) as being entirely anticipated by Ashkenazi (6,342,369).

Ashkenazi is a proper reference under 102 (e), since it is to "another" and was filed on May 14, 1998, prior to the June 12, 1998 date which applicant claims benefit of in the instant application.

Ashkenazi discloses an antibody (3F11.39.7) which binds to Apo-2 and cross-reacts with DR4. See col. 48, lines 46-62. This antibody blocks apoptosis and also has agonistic activity (col. 31, lines 41-48 and col. 48, lines 36-45).

As to the instant claims to DNA sequences encoding the antibody, vectors and host cells and use thereof, as well as to various types of antibody constructs (e.g. humanized), and conjugates of such antibodies, all of these aspects are taught by Ashkenazi. See especially col. 31, line 5 - col. 37, line 8.

Claim 12 is included because the 3F11.39.7 antibody of Ashkenazi has the binding characteristics of the three recited antibodies, in accord with applicant's definition of "cross-reactivity" (para. Spanning pp. 21-22) and Table 2.

Claims 1-12 and 15-21 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. As noted supra, Ashkenazi (6,342,369) has invented the same subject matter.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, Ph.D., whose telephone number is (703) 308-3976. The examiner can normally be reached on Monday-Thursday from 8:00 a.m. to 5:30 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (703) 308-3973. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

D. Saunders:jmr

October 8, 2002

David A. Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 182-1644